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S & F Ref: 442612

ORIGINAL

AUSTRALIA

Patents Act 1990

PROVISIONAL SPECIFICATION FOR THE INVENTION ENTITLED:

Control of Supplied Pressure in Assisted Ventilation

Name and Address of Applicant: ResMed Limited, an Australian company, ACN 003 765 142, of 82-84 Waterloo Road, North Ryde, New South Wales, 2113, AUSTRALIA

Inventor's Name: Michael Berthon-Jones and John Deacon Wickham

This invention is best described in the following statement:

Field of the Invention

This invention relates to Non Invasive Positive Pressure Ventilation (NIPPV) treatment apparatus for the provision of assisted ventilation. Particularly, the invention concerns the control of treatment pressure supplied to a subject.

Background Art

NIPPV apparatus function to supply a patient with a supply of clean breathable gas (usually air, with or without supplemental oxygen) at a therapeutic pressure or pressures, at appropriate times during the subject's breathing cycle. The therapeutic pressure is also known as the ventilation pressure.

NIPPV apparatus typically include a flow generator, an air filter, a mask, an air delivery conduit connecting the flow generator to the mask, various sensors and a microprocessor-based controller. The flow generator may include a servo-controlled motor and an impeller. The flow generator may also include a valve capable of discharging air to atmosphere as a means for altering the pressure delivered to the patient as an alternative to motor speed control. The sensors measure, amongst other things, motor speed, gas volumetric flowrate and outlet pressure. The apparatus may optionally include a humidifier in the air delivery circuit. The controller may include data storage capacity with or without integrated data retrieval and display functions.

In this specification, NIPPV apparatus will be referred to as "assisted ventilation devices" which, in the broadest form, need not include all of the component features mentioned above.

Assisted ventilation devices are used for the treatment of many conditions, for example respiratory insufficiency or failure due to lung, neuromuscular or musculoskeletal disease and diseases of respiratory control.

Common to all forms of assisted ventilation is the need to control the pressure being applied to the patient. It is a known prior art technique to detect the peak pressure and compare it against a maximum threshold value. If the threshold value is exceeded an alarm state occurs, and corrective action may be taken. This corrective action can be a short-term reduction in supplied pressure, followed by an increase back to the previous pressure.

Summary of the Invention

The present invention is directed to providing an alternative, advantageous approach to the problem of overpressure.

The invention discloses a method for detecting the occurrence of a potential or actual overpressure during assisted ventilation, comprising the steps of determining a relatively longterm average of ventilation pressure, and determining whether the average approaches or exceeds a threshold value as being indicative of a potential or actual overpressure occurring.

The invention further discloses a method for controlling operation of an assisted ventilation device supplying pressurised gas to a patient, the method comprising the steps of:

measuring the current delivered pressure;

determining a relatively longterm average of the measured pressure;

comparing said average against a threshold value, and if the threshold value is approached or exceeded, then assessing that an alarm state is occurring; and

if an alarm state is occurring, controlling the pressure supplied by the device.

The invention yet further discloses assisted ventilation apparatus for detecting a potential or actual overpressure condition, comprising:

a blower to supply pressurised gas to a conduit, and in turn to a patent mask for connection with the entrance to a patient's airways;

a pressure sensor to detect the delivered pressure of gas in the conduit or at the mask, and provide a signal thereof; and

a controller receiving the pressure signal and having control over the operation of the blower, and operable to determine a relatively longterm average of the pressure signal, compare the average against a threshold value, and if the threshold value is approached or exceeded, to assess that an alarm state exists and control the blower and thus the supplied pressure.

In one preferred form, on the occurrence of an alarm state, the assisted ventilation apparatus issues an alarm. Additionally or alternatively, the blower can be controlled to be switched-off or to be placed in a low pressure standby mode (for example 4 cmH_20).

Yet alternatively or additionally, the blower can be controlled to limit or reduce the supplied pressure. The reduction can be a non-linear function of time and/or pressure. Particularly, the degree of control can be stronger as the threshold value is approached.

The longterm average can, in one form, be of the order of minutes. Alternatively, the average can be over ten or more breaths.

The threshold can be required to be exceeded for a period of time before the alarm state is assessed as occurring.

The invention is advantageous in that it approaches the problem of overpressure from a relatively longer time scale than in the prior art. This is considered to be a more appropriate approach to the medical conditions that attend overpressure in assisted ventilation. For example, sustained overpressure causes a decrease in cardiac output, which would go largely untreated by the prior art arrangement discussed above.

Brief Description of the Drawings

Fig. 1 is a schematic block diagram of a representative assisted ventilation device, in the form of NIPPV apparatus;

Fig. 2 is a schematic block diagram of an overpressure detection circuit;

Fig. 3 shows traces of treatment pressure with time and the operation of an embodiment of the invention; and

Fig. 4 shows further traces of treatment pressure with time and the operation of an embodiment of the invention.

Description of Preferred Embodiments

An assisted ventilation device embodying one form of the invention is shown in Fig. 1, in which a blower comprising a motor 20 and an impeller 10, supplies breathable gas to a mask 11 for communication with a subject's airway via a delivery tube 12 and exhausting to atmosphere via an exhaust 13. Airflow at the mask 11 is measured using a pneumotachograph 14 and a differential pressure transducer 15. The mask flow signal from the transducer 15 is sampled by a microprocessor 16. Mask pressure is measured at a port 17 using a pressure transducer 18. The pressure signal from the transducer 15 is also sampled by the microprocessor 16. The microprocessor 16 sends an instantaneous mask pressure request signal to a servo 19, which compares the pressure request signal with the actual pressure signal from the transducer 18 to control a motor 20 driving the blower 10. The microprocessor's settings can be adjusted via a serial port 21.

It is to be understood that the mask could equally be replaced with a tracheotomy tube, endotracheal tube, nasal pillows, or other means of making a sealed connection between the air delivery means and the subject's airway.

Generally, the microprocessor 16 determines the long-term average of the actual treatment pressure, $\bar{P}$, and compares this against a threshold or maximum value, $\bar{P}_{max}$. If the threshold value is exceeded then corrective action may be taken. The corrective action can be to issue an alarm, to switch-off the assisted ventilation device, to reduce

[illegible] of which is described in more detail below.

In one embodiment, the invention is implemented in hardware, as shown in Fig. 2.

As shown in Fig. 2, the circuitry 30 receives a signal from the pressure transducer 15 indicative of the pressure in the air delivery conduit 12. The signal is amplified by an operational amplifier 32, then low-pass filtered 34 with a time constant of approximately one minute. Longer or shorter time constants would be appropriate depending on how long it was considered safe for the subject to be exposed to a relatively high mean pressure. In one embodiment, the time constant can be varied by way of an operator accessible control. The low-pass filtered signal passes to a comparator 36 where it is compared with a reference pressure signal corresponding to 15 cmH_2O, representing $\overline{P}_{max}$. The output from the comparator passes to both the servo 19 and a resettable monostable/one-shot 38. The resettable monostable/one-shot 30 is set to 38 seconds. Longer or short time periods would be suitable for specific assisted ventilation applications.

If the output from the comparator 36 is 'true', an indication that the low-pass filter signal exceeds $\overline{P}_{max}$, a "reduce" pressure signal is sent to the servo 19 (shown in Fig. 1) on line 42. At this point, the resettable monostable/one-shot 38 starts to count down. If the count down reaches zero, then a stop signal is sent to the servo 19 on line 44. The count determines an adjustable tolerance on how long the alarm state has occurred before corrective action is taken. If the output from the comparator 36 is "false", there is no alarm state, and the resettable monostable/one-shot 38 is reset.

In another embodiment, the invention is implemented in software, as follows.

Referring once again to Fig. 1, the microprocessor 16 receives a signal representing mask pressure from the transducer 18. The microprocessor 21 controls the

servo 19 such that the desired treatment pressure achieved satisfies the following equation:

$$P = P_0 + k.A.f(v,t) \qquad [1]$$

where:

P is the pressure setting for the blower (degree of support) (cmH_20);

P_0 is a constant, the baseline pressure, chosen, for example, to keep the upper airway open, or to balance intrinsic PEEP (cmH_2O);

In one form,

$$k = 1. \qquad [2a]$$

In other forms,

$$k = k', \text{ low pass filtered with time constant of 5 seconds} \qquad [2b]$$

where

$$k' = \begin{cases} 0, & \bar{p} \geq 15\ cmH_2O \\ 0.1, & \bar{p} = 14.9\ cmH_2O \\ 1, & \bar{p} \leq 14.5\ cmH_2O \end{cases} \qquad [3]$$

and linearly in between.

The purpose of making k nonlinear on $\bar{p}$ is to provide strong control as $\bar{P}_{max}$ is approached, with less effect further away from $\bar{P}_{max}$. The purpose of low pass filtering is to reduce distortion of the within-breath pressure-time profile.

The pressure modulation amplitude, A ($cm\ H_2O$) is given by:

$$A = g\int(\dot{V}_e - V_{TGT})dt \qquad [4]$$

where g is a constant, $\dot{V}_e$ is the minute ventilation, and V_{TGT} is the target ventilation. A may be truncated to lie between A_{max} and A_{min}.

[illegible] at least one of time t and respiratory airflow v, chosen to produce the desired pressure waveform. A range of functions is known to those skilled in the art. One example function is :

$$f(v,t)=\begin{cases}1, & v>0\\ 0 & otherwise\end{cases} \qquad [5a]$$

corresponding to a spontaneous mode bi-level ventilator. Another example function is:

$$f(v,t)=\begin{cases}1, & t'<T_i\\ 0, & otherwise\end{cases} \qquad [5b]$$

where

t' = t modulo T_{tot}

T_i = duration of inspiration

T_{tot} = duration of expiration

Corresponding to a "timed-mode" bilevel ventilator, with

$P = P_o$ during expiration; and

$P = P_o + A$ during inspiration

A number of simulations have been performed to demonstrate an embodiment of the invention in practise.

In Fig. 3, there is a sustained rise in peak pressure. In the top trace is shown the effect without the use of the present invention. The mean pressure exceeds a chosen $\overline{P}_{max}$ of 15 cmH_2O, which is undesirable. In the second trace, this is corrected by an embodiment of the invention, where the mean pressure is kept close to $\overline{P}_{max}$. The bottom trace shows the factor "k", and how it decreases from unity to approximately 0.5.

In Fig. 4, there is a transient rise in peak pressure. In the top trace, even without the practise of invention, the mean pressure closely approaches but does not exceed $\overline{P}_{max}$, which is permissible, even though the instantaneous pressure goes very high. With the invention practised, (second trace), the resultant pressure is little affected, because k remains close to unity (bottom trace)

In this embodiment, as the mean pressure threshold is approached, the degree of assistance is gradually reduced or limited. In another embodiment, both the baseline pressure, Po, and amplitude of ventilatory support, A, are progressively reduced as the mean pressure, $\overline{P}$, approaches the desired threshold pressure, $\overline{P}_{max}$.

The invention has been described with reference to a number of non-limiting examples, and it will be appreciated that the invention can be embodied in numerous other forms.

DATED this Sixth Day of May, 1999

ResMed Limited

Patent Attorneys for the Applicant

SPRUSON & FERGUSON

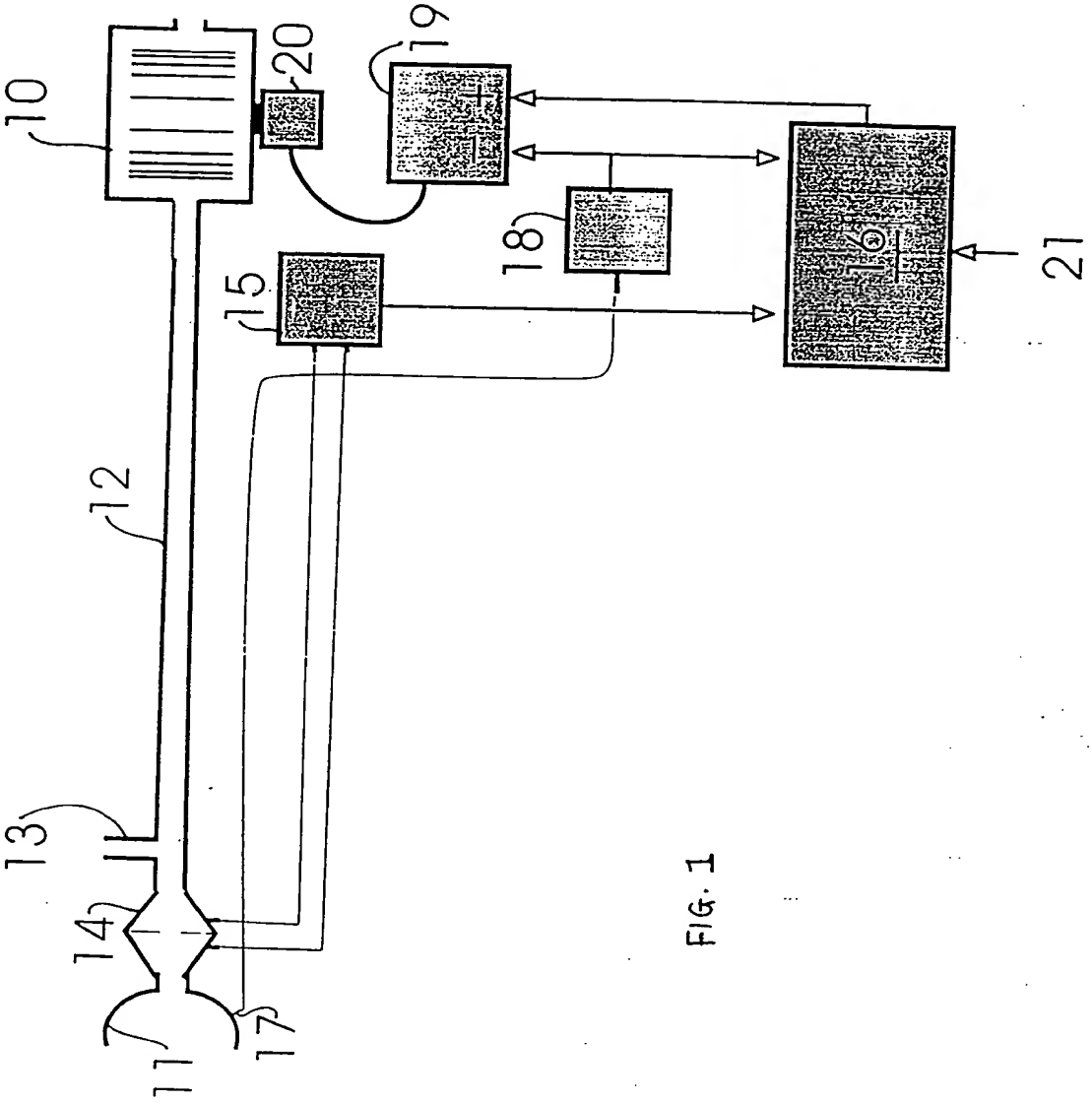


FIG. 1

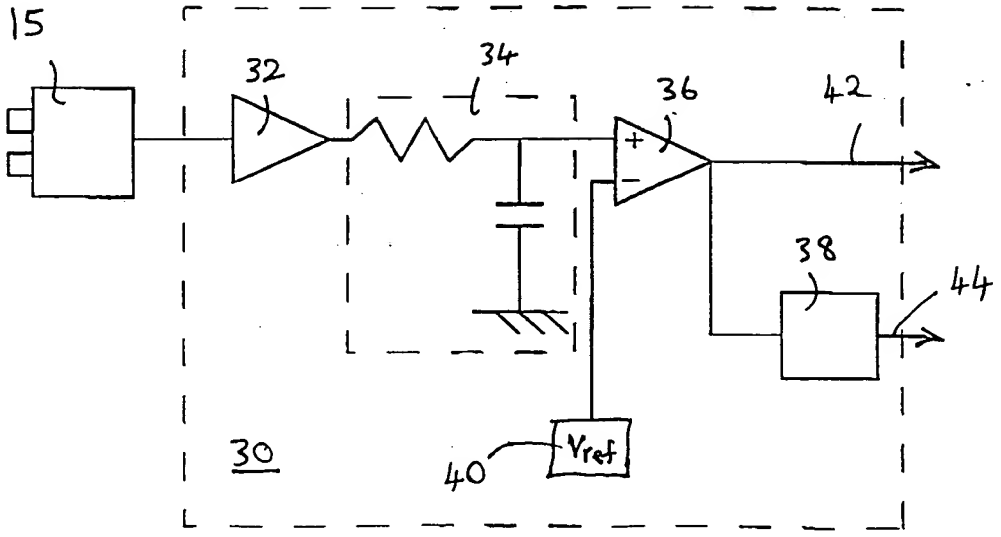
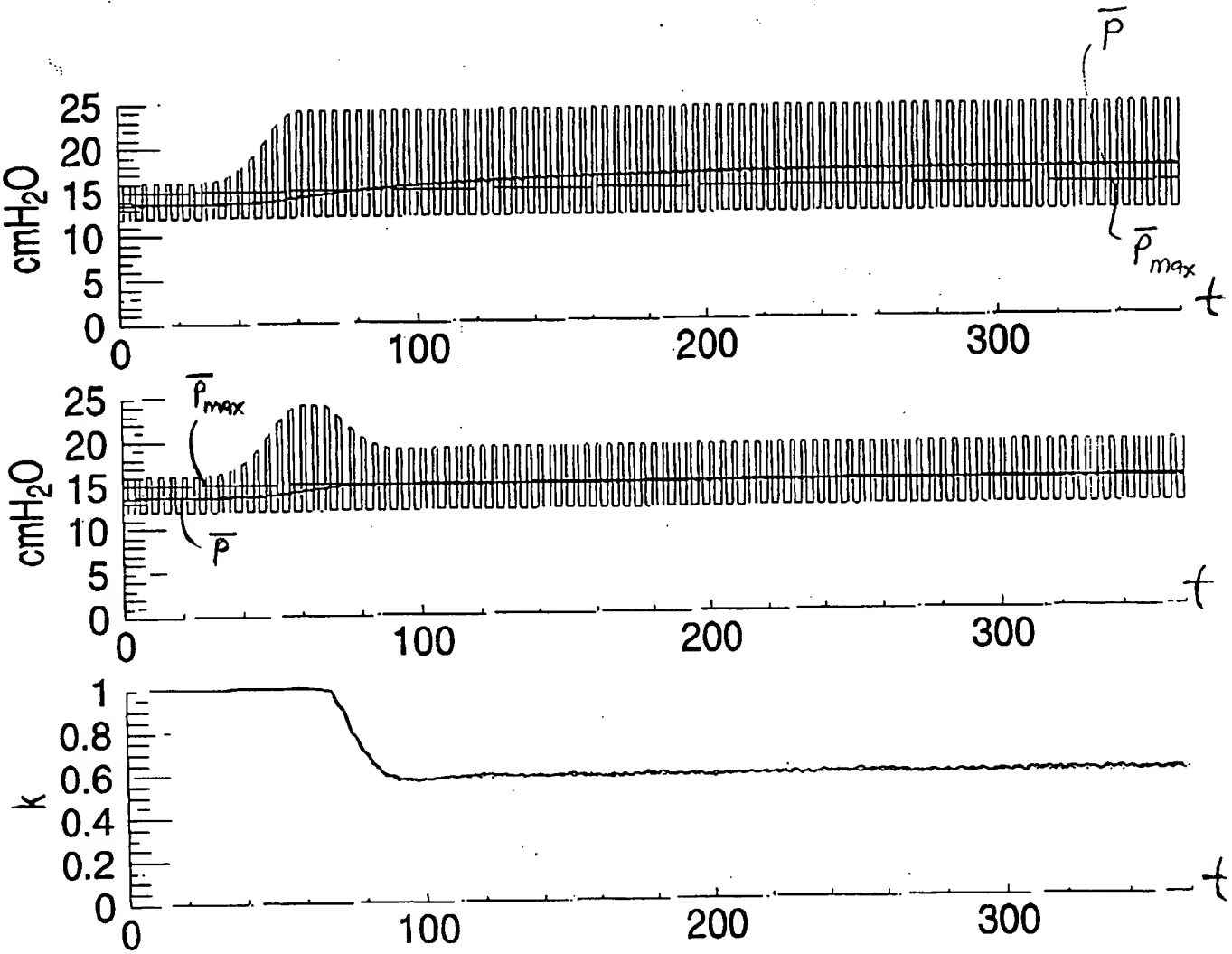


FIG. 2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$\bar{P}_{max}$
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FIG. 3

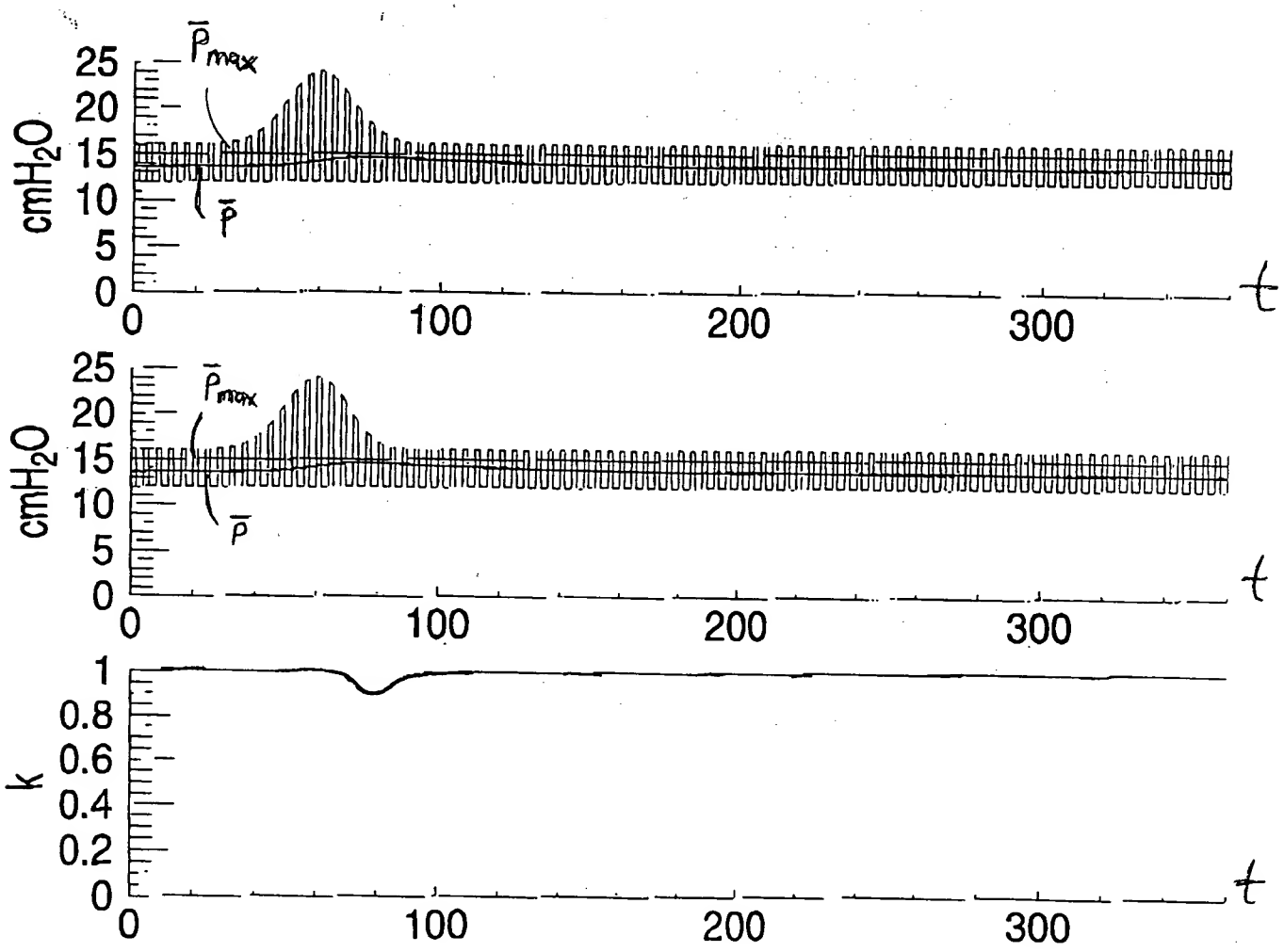
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FIG. 4